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BD of Appeal AF/1600

CASE 4-30028A/PCT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE PCT NATIONAL STAGE APPLICATION OF
PORTMANN ET AL.

INTERNATIONAL APPLICATION NO: PCT/EP 98/03427

FILED: 8 JUNE 1998

U.S. APPLICATION NO: 09/125,329 ✓

35 USC §371 DATE: 8 SEPTEMBER 1998

FOR: CRYSTAL MODIFICATION OF 1-(2,6-DIFLUOROBENZYL)-1H-
1,2,3-TRIAZOLE-4-CARBOXAMIDE AND ITS USE AS
ANTIPILEPTIC

Art Unit: 1625

Examiner: P. Morris

Appeal No.: 2003-1199

Decided: NOVEMBER 17, 2003

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

COMMUNICATION

Sir:

In compliance with 37 C.F.R. §1.56, this Communication is intended to make of record the prosecution history to date of the parallel "continuation" of the subject U.S. application, viz., U.S. Application No. 10/294,408. In this connection, U.S. Application No. 10/294,408 will be allowed to go abandoned subsequent to the receipt of the anticipated Notice of Allowance and the granting of a U.S. patent regarding the subject U.S. application in view of the recent Board decision which reversed all of the rejections on appeal.

In the "first" Official Action regarding U.S. Application No. 10/294,408, the Examiner lodged the same three rejections which were recently reversed by the Board regarding the subject U.S. application and a "same invention double patenting" rejection over the claims of the subject U.S. application. Despite the presentation of salient arguments, the Examiner maintained all of the rejections and made them final. In response thereto, the previous arguments were reiterated and additional arguments were presented. However, the Examiner

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issued an Advisory Action which maintained the "finality" of the rejections. Shortly thereafter, the Examiner withdrew the Final Rejection and issued a "new" Office Action.

In addition to the "four" rejections that were maintained in the Advisory Action, the "new" Office Action additionally contains: 1) a 35 U.S.C. §102(b) rejection; 2) a "new" 35 U.S.C. §103(a) rejection; 3) two rejections under the first paragraph of 35 U.S.C. §112; and 4) a rejection under the second paragraph of 35 U.S.C. §112. In addition, and with regard to the "original" 35 U.S.C. §103(a) rejection and the "obviousness-type" double patenting rejection over Claims 1-21 of USP 4,789,680, said rejections have been amended so as to rely on "three" additional secondary references.

First of all, rejections 1) and 4) were lodged and subsequently withdrawn on appeal regarding the subject application. As to rejection 1), it should be noted that the CAFC has consistently held that "novel" crystalline forms of a compound are not anticipated by a crystalline form of the compound in the prior art. Moreover, in Glaxo, Inc. v. Novopharma Ltd., 34 USPQ2d 1565 (Fed. Cir. 1995), the district court held that "new" crystalline forms of a compound are not inherent by the disclosure of a crystalline form in the prior art and the Federal Court affirmed the district court decision.

As to rejection 2), since the publication date of the primary reference, viz., USP 6,156,907, is subsequent to the filing date of Appellants' Swiss priority application, the benefit of which they are entitled to under 35 U.S.C. §119, this reference can neither be applied alone nor in combination with one or more secondary references in rejecting any of the claims of U.S. Application No. 10/294,408.

With regard to that portion of rejection 3) which is directed to a "non-enabling" rejection under the first paragraph of 35 U.S.C. §112 for lack of data to establish efficacy in treating epilepsy, this rejection was lodged and subsequently withdrawn in the "related" case, now issued as USP 6,455,556. In this connection, and as set forth in *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990), if the prior art teaches the identical chemical structure, the properties Applicant discloses are necessarily present.

As to the remaining portion of rejection 3), i.e., the rejection under the first paragraph of 35 U.S.C. §112 on the grounds that the specification is devoid of any "phase diagrams", it is not believed that they are necessary to satisfy the "written description" requirement of 35 U.S.C. §112 when claiming "new" crystalline forms. The absorption pattern of IR and Raman spectra and the other characterizing features for each of the crystalline forms which are disclosed in the specification clearly show that the inventors had possession of the claimed invention.

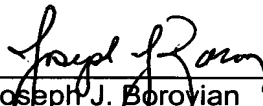
With respect to the "three" additional secondary references, it should be noted that the Chemical & Engineering News reference is a very recent publication and, therefore, cannot be applied in rejecting any of the claims of U.S. Application No. 10/294,408. As to the remaining secondary references, viz., the U.S. Pharmacopia and Concise Encyclopedia Chemistry references, and as was the Chemical & Engineering News reference, they are being relied upon as teaching that: "at any given temperature and pressure, only one crystalline form of a compound is thermodynamically stable". First of all, "thermodynamic stability" is not a feature that is present in any of the claims of U.S. Application No. 10/294,408. Secondly, it is not seen how this teaching is relevant to the patentability of "novel" crystalline forms. In short, it is clear that the additional secondary references do not cure the critical deficiencies of the Meier I or Meier II references.

A completed PTO-1440 form, together with a copy of the references listed therein, is enclosed.

In view of the foregoing, it is clear that none of the issues raised by the Examiner in the "new" Office Action regarding U.S. Application No. 10/294,408 adversely impacts or has any bearing on the recent Board decision regarding the subject application.

Respectfully submitted,

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Encls.: PTO-1449 form (incl. copies of references)
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